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PART OF THE ARES SERONO GROUP

SERONO LABORATORIES, INC.
100 LONGWATER CIRCLE
NORWELL, MA 02061 / USA
(800) 283-8000
TEL (781) 982-9000
FAX (781) 871-6724

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July 23, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

RE: Docket No. 98N-0222
GUIDANCE FOR INDUSTRY:
DISSEMINATION OF INFORMATION ON UNAPPROVED/NEW USES
FOR MARKETED DRUGS, BIOLOGICS, AND DEVICES

Dear Ladies/Gentlemen:

In response to the above-mentioned draft guidance document which was released for comment on June 8, 1998, attached are comments submitted by Serono Laboratories, Inc. The comments consist of an additional sentence, presented in bold text under the relevant section heading, below.

Section 99.101 Information that may be disseminated.

(5) Not be derived from clinical research conducted by another manufacturer, unless the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination. **Research conducted by an independent academic or similar organization, where the rights to such data were not obtained by a manufacturer prior to the conduct of the research, shall be information which can be disseminated by any manufacturer(s), if the information otherwise meets the standards for dissemination pursuant to this regulation and is legally available to the manufacturer for such use.**

Should you have any questions regarding this submission, please contact the undersigned.

Yours sincerely,

Howard J. Fingert, M.D., F.A.C.P.
Director,
Drug Safety, Advertisement and Promotion
Serono Laboratories, Inc.

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